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LICATA & TYRRELL

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## FACSIMILE COVER SHEET

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November 3, 2003

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**TO: Examiner Wilder (TC1600)**

**GROUP: 1637**

**FAX NUMBER: 703-872-9306**

**ATTORNEY DOCKET NO.: DEX-0249**

**SERIAL NO.: 10/082,830**

**FILED: October 29, 2001**

**NUMBER OF PAGES:**

**MESSAGE:** Attached please find Amendment Transmittal Letter, Reply to Restriction Requirement and Certificate of Transmission by Facsimile.

**Kathleen A. Tyrrell, Registration No. 38,350**

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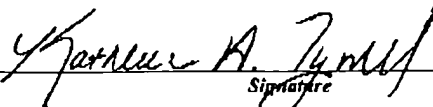
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<b>CERTIFICATE OF TRANSMISSION BY FACSIMILE (37 CFR 1.8)</b>			Docket No.
Applicant(s): Sun et al.			DEX-0249
Serial No. 10/082,830	Filing Date October 29, 2001	Examiner Wilder, Cynthia B.	Group Art Unit
Invention: Compositions and Methods Relating to Breast Specific Genes and Proteins			
<p>I hereby certify that this <u>Reply to Restriction Requirement</u> (Identify type of correspondence)</p> <p>is being facsimile transmitted to the United States Patent and Trademark Office (Fax. No. <u>703/872-9306</u>)</p> <p>on <u>November 3, 2003</u> (Date)</p> <p><u>Kathleen A. Tyrrell</u> (Typed or Printed Name of Person Signing Certificate)</p> <p><u>Kathleen A. Tyrrell</u> (Signature)</p> <p><b>Note: Each paper must have its own certificate of mailing.</b></p>			

<b>AMENDMENT TRANSMITTAL LETTER (Large Entity)</b>				Docket No. <b>DEX-0249</b>	
Applicant(s): Sun et al.					
Serial No. <b>10/082,830</b>	Filing Date <b>October 29, 2001</b>	Examiner <b>Wilder, Cynthia B.</b>		Group Art Unit <b>1637</b>	
Invention: <b>Compositions and Methods Relating to Breast Specific Genes and Proteins</b>					
<u><b>TO THE COMMISSIONER FOR PATENTS:</b></u>					
Transmitted herewith is an amendment in the above-identified application.					
The fee has been calculated and is transmitted as shown below.					
<b>CLAIMS AS AMENDED</b>					
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST # PREV. PAID FOR	NUMBER EXTRA CLAIMS PRESENT	RATE	ADDITIONAL FEE
<b>TOTAL CLAIMS</b>	19 -	20 =	0 x	\$18.00	\$0.00
<b>INDEP. CLAIMS</b>	2 -	3 =	0 x	\$86.00	\$0.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
<b>TOTAL ADDITIONAL FEE FOR THIS AMENDMENT</b>					<b>\$0.00</b>
 <input checked="" type="checkbox"/> No additional fee is required for amendment. <input type="checkbox"/> Please charge Deposit Account No. _____ in the amount of _____ <input type="checkbox"/> A check in the amount of _____ to cover the filing fee is enclosed. <input checked="" type="checkbox"/> The Director is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. <b>50-1619</b> <input checked="" type="checkbox"/> Any additional filing fees required under 37 C.F.R. 1.16. <input checked="" type="checkbox"/> Any patent application processing fees under 37 CFR 1.17.					
 _____ Kathleen A. Tyrrell, Reg. No. 38,350			Dated: <b>November 3, 2003</b>		
Licata & Tyrrell P.C. 66 East Main Street Marlton, New Jersey 08053 Tel : 856-810-1515 Fax: 856-810-1454			<div style="border-bottom: 1px solid black; margin-bottom: 10px;">I certify that this document and fee is being deposited on _____ with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</div> <div style="border-bottom: 1px solid black; margin-bottom: 10px; text-align: center;">Signature of Person Mailing Correspondence</div> <div style="border-bottom: 1px solid black; text-align: center;">Typed or Printed Name of Person Mailing Correspondence</div>		
CC:					

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Attorney Docket No.: DEX-0249  
Inventors: Sun et al.  
Serial No.: 10/082,830  
Filing Date: October 29, 2001  
Examiner: Wilder, Cynthia B.  
Group Art Unit: 1637  
Title: Compositions and Methods Relating to  
Breast Specific Genes and Proteins

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## Certificate of Facsimile Transmission

I hereby certify that this document is being facsimile  
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the date shown below.

On November 3, 2003

  
Kathleen A. Tyrrell, Registration No. 38350

Mail Stop  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Reply to Restriction Requirement

This is a reply to the Restriction Requirement mailed  
October 2, 2003 setting a one (1) month statutory period for  
response. Please enter the following remarks into the record.

Remarks begin at page 2.

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#### REMARKS

Claims 1-17 are pending in the instant patent application. Claims 1-17 have been subjected to a Restriction Requirement as follows:

Group I, claims 1-5, 7-9, and 15, drawn to an isolated nucleic acid, classified in class 536, subclass 23.1;

Group II, claims 6 and 14, drawn to a hybridization method for determining the presence of breast specific nucleic acid (BSNA), classified in class 435, subclass 6;

Group III, claim 10, 11 and 15, drawn to an isolated polypeptide, classified in class 530, subclass 350;

Group IV, claims 12, drawn to an antibody, classified in class 424, subclass 130.1;

Group V, claims 12, 14, drawn to a protein binding assay for determining the presence of breast specific nucleic acid, classified in class 435, subclass 7.1;

Group VI, claim 16, drawn to a method of treating a patient with drug, classified in class 514, subclass 12; and

Group VII, claim 17, drawn to a vaccine, classified in class 424, subclass 184.1.

The Examiner suggests that these Groups are distinct, each

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from the other.

Specifically, with respect to Groups I, III, IV and VII, the Examiner suggests that the claims of these Groups are drawn to unrelated products.

With respect to Groups I and II, IV and Groups III, IV and V, VI, the Examiner has acknowledged their relationships as product and process of use. However, the Examiner suggests that these Groups are distinct because the products can be used in materially different processes.

With respect to Groups II, V and VI, the Examiner suggests that the Groups are unrelated methods.

Further, the Examiner suggests that each of the above Groups reads on patentably distinct sequences and has requested that Applicants further elect a single amino acid or single nucleic acid sequence.

At the outset, clarification is requested with respect to claims encompassed in Group V. The Examiner suggests that Group V, claims 12, 14 are drawn to a protein binding assay. It is respectfully pointed out, however, that neither of these claims are drawn to this subject matter. Further, claims 12 and 14 were included in Groups IV and II, respectively. Applicants believe that the Examiner meant to include only claim 13 in Group V.

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However, clarification of the record by the Examiner is respectfully requested.

Further, Applicants respectfully traverse this Restriction Requirement.

MPEP §803 provides two criteria which must be met for a restriction requirement to be proper. The first is that the inventions be independent or distinct. The second is that there would be a serious burden on the Examiner if the restriction is not required. A search of prior art relating to an elected nucleic acid, polypeptide or antibody would also reveal any references teaching uses for the nucleic acid, polypeptide or antibody. Accordingly, Applicants believe that searching of all the claims, at least when limited to elected nucleic acids, polypeptides, or antibodies, is overlapping and would not place an undue burden on the Examiner if the Restriction is not made.

Thus, since this Restriction Requirement does not meet both criteria as set forth in MPEP § 803 to be proper, reconsideration and withdrawal of this Restriction Requirement is respectfully requested.

In addition, with respect to the election of a single sequence, MPEP § 803.04 clearly states that a reasonable number of nucleotide sequences, normally ten sequences, can be claimed

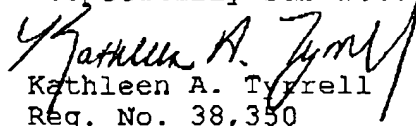
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in a single application. Accordingly, withdrawal of this sequence election requirement and reconsideration to include a more reasonable number of at least 10 sequences in accordance with MPEP § 803.04 is also respectfully requested.

However, in an earnest effort to advance the prosecution of this case Applicants elect Group I, claims 1-5, 7-9 and 15 with traverse. Further, Applicants elect SEQ ID NO:99 encoding SEQ ID NO:224, with traverse. Since SEQ ID NO:98 is a sub-sequence of SEQ ID NO: 99, it is respectfully requested that at least SEQ ID NO:98 be included in this case as well.

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Respectfully submitted,

  
Kathleen A. Tyrrell  
Reg. No. 38,350

Date: November 3, 2003

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